

REMARKS

Upon entry of the amendments herein, claims 21-62 and 71-79 are pending in the application. Claims 21, 29, 36-39, 41, 42, 44-47, 50, 55 and 62 (first instance) have been amended; claims 30, 62 (second instance) and 63-70 have been cancelled; and claims 71-79 have been added herein. Also, a number of amendments have been made to the specification to correct inadvertent errors. No new matter has been introduced by any of the amendments made herein.

Among the amendments to the specification is one to the cross-reference to related applications. The present application was not filed to resume prosecution of subject matter withdrawn in the parent due to a restriction requirement. Rather, it was filed to prosecute additional subject matter to which Applicant is entitled but which was neither originally claimed in the parent nor claimed in the patent that issued from said parent. Accordingly, the parent application is properly called a "continuation," not a "divisional" of application Serial No. 09/094,402.

The Examiner has leveled two objections to the drawings. In the first instance, the Examiner notes the phrase "first diameter d" on page 12, line 21 and objects because said

diameter is not shown in Figure 1 or any of the other figures. With respect to Figure 5, the Examiner objects because reference number "1" does not have a lead line. Applicant submits herewith a revised version of Figure 1 wherein the "first diameter d" is indicated and a revised version of Figure 5 which has a lead line for the reference number. It is requested that the objections to the drawings be withdrawn on the basis of this response.

The Examiner has leveled a number of objections to the claims on the basis of "informalities." The informalities have been addressed by the amendments herein. Applicant has made further amendments to the claims in the interest of correcting additional informalities and inadvertent errors.

It has come to the attention of Applicant's agent that a numbering error was made when claims 62-70 were added in Applicant's March 13, 2002 Supplemental Amendment and Response. At that time, two claims numbered 62 were inadvertently added. In the present communication, independent claim 62 has been retained, with further amendment (in response to the Examiner's objection). The second, dependent claim 62 and all eight subsequent, misnumbered claims have been cancelled and replaced with properly numbered claims 71-79. New claim 71 corresponds to previously added, dependent claim 62. New claims 72-79 correspond to previously added claims 63-70, respectively. The

new claims reflect amendments to claim dependencies as appropriate; otherwise these claims are identical to the corresponding, now-cancelled claims. The Examiner previously indicated that claim 62 (both instances), as well as claims 63-70, are allowable. Retained independent claim 62 and new claims 71-79 are thus also allowable.

Claims 21-34, 36 and 40-46 have been rejected under 35 USC §112, first paragraph as containing subject matter not sufficiently described in the specification to convey Applicant's possession of the claimed invention at the time of filing.

More particularly, claims 21, 44 and 46 have been rejected under this section of the statute for reciting a stent having "square edges." It is not precisely understood by Applicant what distinction the Examiner is making between "end" and "edge" in this context. What is meant by either "square ends" or "square edges" is that the present stents do not have undesirable skewed or otherwise projecting end portions, either in the crimped or expanded state. This feature is clearly shown in the figures and also disclosed and verbally defined in the instant specification: "The end portion of the device ends substantially tranverse to the central axis of the device..." (page 16, lines 12 and 13). This notwithstanding, in the interests of laying this issue to rest and expediting

prosecution of the application claims 21, 44 and 46 have been amended by replacement of the language in question with language that the Examiner acknowledges to be present in the specification and, hence, appropriate.

The Examiner further asserts that the recitation of crossing segments in claim 24 is not supported in the specification or drawings; Applicant emphatically disagrees with this assessment. Again, it is not understood what that Examiner feels is lacking in the instant disclosure. It can clearly be seen from, for example, Figures 6 and 7 that the segments can cross each other at the points of interconnection. As another example, original claim 7 (which must be considered part of the disclosure) recites helical patterns running in different directions along the longitudinal axis. It must be appreciated from this that the segments can cross each other as they traverse the length of the stent.

The Examiner further alleges that claims 29, 36 and 41 constitute new matter because there is no support for a variation in the "circumferential dimension" along the helical length. These claims have been amended by deletion of the subject matter in question; the rejection is moot.

Claims 21-34, 36 and 40-54 have been rejected under 35 USC §112, second paragraph as being indefinite. The issue raised with respect to the word "edge" in claims 21, 44 and 46 is

rendered moot by Applicant's amendment herein to the claims in response to the §112, first paragraph rejection of the same claims.

Claims 28-30, 36, 40 and 41 were rejected in the basis of a "circumferential dimension" issue related to the one raised by the Examiner in connection with the §112, first paragraph rejections. More generally this time, the Examiner queries as to how this dimension is being measured. The question with respect to variance of the dimension is moot in light of the cancellation of claims and elimination of pertinent subject matter from other rejected claims. Furthermore, by elimination of this subject matter, the question raised by the Examiner "How is it [the circumferential dimension] parallel to the circumference of the stent and varying along its helical length?" is moot. It is clear what the circumference of the stent is and, therefore, what is meant by a dimension parallel thereto. The Examiner's final question as to whether the variance is in the crimped or expanded configuration is also now moot.

The Examiner further alleges that claim 47 is indefinite for recitation of the phrase "the longitudinal axis" without sufficient antecedent basis. The claim has been amended herein to address this issue.

Claims 21-23, 26-46 and 55-61 have been rejected under 35 USC §102(e) as being anticipated by US 5,925,061 to Ogi, et al. The Examiner primarily relies on Figure 7 of Ogi in rejecting base claims 21, 35, 37 and 55 and claims dependent therefrom. Applicant disagrees with the Examiner's assessment.

The Examiner arbitrarily designates the bottom two rows of peaks and valleys in Ogi Figure 7 as corresponding to the first segment of the instant stent and the above two rows as corresponding to the instant second segment, said Ogi features supposedly corresponding to elements of the instant claims. However, as disclosed and claimed in the Ogi patent, and as summarized in the patent abstract, the stent of Ogi "includes helical windings in a single helix, which [windings] are joined by bridges...." The stent of Ogi, as illustrated in Figure 7 and claimed in claim 1, comprises apex-to-apex connections in a single helical element; this is not the stent of the instant application, which comprises two different helically propagating elements. Furthermore, the straight connecting elements of Ogi are not the S-bent connection elements of the instant invention as illustrated, for example, in instant Figure 3. The Examiner is also referred to such instant disclosure as that on page 9, lines 2-4 wherein a feature of the instant stent is disclosed to be that "successive connection elements are mutually connected by an elongated member which has a greater length than the

linear distance between said connection elements...." Thus, the disclosure of Ogi cited by the Examiner does not at all anticipate the stents recited in the instantly rejected base claims. The Examiner's subsequent citation of alleged disclosure by Ogi of the particular features recited in the instant claims dependent from the rejected base claims is immaterial in light of the fact that the Ogi disclosure does not even read on the more general features recited in the rejected base claims. Withdrawal of the rejection is respectfully requested.

Claims 47-54 have been rejected under 35 USC §102(e) as being anticipated by US 6,013,854 to Moriuchi. The Examiner refers to Figures 5 and 6 of Moriuchi and asserts that "Moriuchi discloses a stent with all the elements of claim 47." Applicant disagrees with the Examiner's assessment.

As is clear from the cited figures and the disclosure in the specification and claims, the helical frame structure of Moriuchi is in the form of sharp turns, i.e., a zigzag pattern, not in the undulating or wavy form of the helical element(s) of the instant stent. These structural features of the Moriuchi stent illustrated in Moriuchi Figures 5 and 6 are emphasized in the language of the Moriuchi base claims, 1 and 15. In claim 1, it is recited that the helical element is comprised of "wire segments in a shape of a repeating '<' which extend

helically...." Claim 15 is directed to a stent "comprising a frame structure. . .possessing a zigzag shape that extends helically." The zigzag, sharp-turned helical element of Moriuchi is not the undulating, curved element of the instant stent. Further, the Moriuchi stent does not have the "connecting segments connecting proximal portions of the first helically advancing pattern to distal portions of the...pattern" recited in the rejected instant claims. The particular design of the instant stents in these regards contributes to the properties of said stents that distinguish them from previously known stents such as those of Moriuchi.

Not
Claimed

The Examiner has acknowledged that both instances of claim 62, as well as claims 63-70 (now claims 62 and 71-79), are allowable. The Examiner further indicated that claims 24 and 25 would be allowable if the indefiniteness rejections were addressed and if said claims were further amended to include the limitations of the rejected base claim and any intervening claims. The indefiniteness issues have been addressed herein. However, in view of the comments and arguments above, there is no need to combine the limitations of claim 24 or 25 with the rejected base claim to distinguish the claimed invention over the cited prior art. In fact, all of the pending claims are patentably distinct over said prior art. Furthermore, the claims have been amended, as appropriate, in response to the

issues raised by the Examiner with respect to informalities and \$112 considerations. Reconsideration and allowance of pending claims 21-62 and 71-79 are respectfully requested. Should any other matters require attention prior to allowance, it is requested that the Examiner contact the undersigned.

The Commissioner is hereby authorized to charge any fees which may be due in connection with this communication to Deposit Account No. 23-1703.

Dated: January 5, 2004

Respectfully submitted,



Richard J. Sterner
Reg. No. 35,372

Applicant's Agent
Customer Number 007470
(212) 819-8200

Agent's Direct Line:
Direct Dial: (212) 819-8783

Enclosures